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Registration Decision

Iodosulfuron-Methyl- Sodium Technical Herbicide

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Overview

Registration Decision for Iodosulfuron-Methyl-Sodium Technical Herbicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of iodosulfuron-methyl-sodium technical herbicide and Tribute Solo 32 DF Herbicide containing the technical grade active ingredient iodosulfuron-methyl-sodium technical herbicide to control certain broadleaf and grassy weeds in field corn.

Current scientific data from the registrant were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document,¹ Proposed Registration Decision PRD2008-06, *Iodosulfuron-Methyl-Sodium Technical Herbicide* (PRD2008-06). This Registration Decision² describes this stage of the PMRA's regulatory process for iodosulfuron-methyl-sodium technical herbicide and Tribute Solo 32 DF Herbicide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2008-06. This decision is consistent with the proposed registration decision stated in PRD2008-06.

For more details on the information presented in this Registration Decision, please refer to PRD2008-06, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration.³ The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive human populations (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Iodosulfuron-Methyl-Sodium Technical Herbicide?

Iodosulfuron-methyl-sodium technical herbicide is a postemergence herbicide, i.e. a herbicide applied after the crop has emerged above the ground. It is applied to field corn using ground application equipment to control broadleaf and grassy weeds. Iodosulfuron-methyl-sodium inhibits the activity of acetolactate synthase (ALS), which is the key enzyme in the biosynthesis of the branch-chain amino acids, isoleucine, leucine and valine. Although the actual sequence of phytotoxic processes is unclear, plant death results from events occurring in response to inhibition of the ALS enzyme.

Health Considerations

Can Approved Uses of Iodosulfuron-Methyl-Sodium Technical Herbicide Affect Human Health?

Iodosulfuron-methyl-sodium technical herbicide is unlikely to affect your health when used according to label directions.

Exposure to iodosulfuron-methyl-sodium technical herbicide may occur through diet (food and water). When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when using iodosulfuron-methyl-sodium technical herbicide products according to label directions.

Iodosulfuron-methyl-sodium technical herbicide caused eye irritation in animals and the end-use product, Tribute Solo 32 DF Herbicide, caused dermal irritation and sensitization in animals. Therefore, the label statement "Warning Skin Irritant, Potential Skin Sensitizer" is required. Iodosulfuron-methyl-sodium technical herbicide did not cause cancer in animals and was not genotoxic. There was also no indication that iodosulfuron-methyl-sodium technical herbicide caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given

daily doses of iodosulfuron-methyl-sodium technical herbicide over longer periods of time were effects on the liver, kidneys and blood parameters. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When iodosulfuron-methyl-sodium technical herbicide was given to pregnant animals, effects on the developing fetus were observed at doses that were not toxic to the mother, indicating that the fetus was more sensitive than the adult animal to iodosulfuron-methyl-sodium technical herbicide. However, these effects occurred only at doses much higher than the doses producing the most sensitive effect in the database, which was used for the risk assessment. Consequently, sufficient protection already exists for the developing fetus. Therefore, there is no need for further reduction in the allowable level of human exposure to iodosulfuron-methyl-sodium technical herbicide as all groups, including sensitive populations, are adequately protected.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the population group that would ingest the most iodosulfuron-methyl-sodium technical herbicide relative to body weight, are expected to be exposed to less than 0.10% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from iodosulfuron-methyl-sodium is not of concern for any population group. Animal studies revealed no acute health effects.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk. Corn residue trials conducted throughout the United States using iodosulfuron-methyl-sodium technical herbicide were acceptable. The MRL for iodosulfuron-methyl-sodium technical herbicide in or on field corn grain has been established in Table II of the *Food and Drugs Act* (15 April 2005).

Occupational Risks From Handling Iodosulfuron-Methyl-Sodium Technical Herbicide

Refer to Regulatory Note REG2004-04, *Iodosulfuron-methyl-sodium*, for a detailed assessment of the toxicological database for iodosulfuron-methyl-sodium technical herbicide and the end-use product, Tribute Solo 32 DF Herbicide.

Environmental Considerations

What Happens When Iodosulfuron-Methyl-Sodium Technical Herbicide Is Introduced Into the Environment?

Iodosulfuron-methyl-sodium technical herbicide is toxic to terrestrial plants; therefore, buffer zones are required during application.

Iodosulfuron-methyl-sodium technical herbicide enters the environment when used as a herbicide on corn. Iodosulfuron-methyl-sodium technical herbicide is slightly persistent in soil and water, while the major breakdown products range from non-persistent to persistent in soil and water. Based on laboratory mobility data, iodosulfuron-methyl-sodium technical herbicide and its major breakdown product would be expected to leach through the soil profile beyond 30 cm with the potential to enter groundwater. Under field conditions at an Ontario site, however, this potential was not realized due to rapid breakdown. Based on low volatility, iodosulfuron-methyl-sodium technical herbicide residues are not expected in the air.

Iodosulfuron-methyl-sodium technical herbicide and its major breakdown product present a low risk to wild mammals, birds, earthworms, bees and other arthropods. As is expected for a herbicide, the end-use product adversely affects terrestrial and aquatic plants in adjacent areas.

Value Considerations

What Is the Value of Tribute Solo 32 DF Herbicide?

Tribute Solo 32 DF Herbicide, a postemergence herbicide, controls both grasses and broadleaf weeds in field corn.

A single application of Tribute Solo 32 DF Herbicide provides effective control of a range of broadleaf and grassy weeds in field corn. It is also compatible with integrated weed management practices and with conventional crop production systems. Since Tribute Solo 32 DF Herbicide is applied after weeds have emerged, farmers can better assess whether the herbicide is necessary or suitable for particular weed species.

Tribute Solo 32 DF Herbicide had been granted conditional registration with one of the conditions that the lowest effective rate for common ragweed be established. The registrant has since decided not to support the claim of common ragweed control. Therefore, this claim has been removed from the Tribute Solo 32 DF Herbicide label. The condition of registration has now been adequately addressed from a value perspective and no further data are required.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Tribute Solo 32 DF Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

- Since there is a concern with users coming into direct contact with iodosulfuron-methyl-sodium technical herbicide on the skin, anyone mixing or loading Tribute Solo 32 DF Herbicide must wear a long-sleeved shirt, pants and chemical-resistant gloves, and anyone applying the product must wear a long-sleeved shirt and pants.

Environment

- TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands) and sensitive aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, wetlands and estuarine/marine habitats).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:	
		Aquatic habitat	Terrestrial habitat
Field sprayer	Corn	1	1

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 The Active Ingredient, Its Properties and Uses

PMRA 1260246 Analytical Profile of Five Typical Production Batches, Code AE F115008, Iodosulfuron-methyl-sodium (Technical Grade Active Ingredient), Aventis, Study identification PA01/071, March 20, 2002, 46 pages, DACO 2.13.3.

2.0 Toxicology

PMRA 855991 Iodosulfuron-Methyl-Sodium. Toxicology-PMRA Registration Requests and Bayer CropScience Waiver requests. Bayer CropScience Inc. Report No.: AE F115008-2004. 21 pages. GLP is N/S. Publication status is N/S., AE F115008-2004, DACO: 4.3.4,4.4.2,4.5.12,4.5.3

3.0 Impact on Human and Animal Health

PMRA 1053449 Attachment 1: Response to DACO 5.8 Clarification. Blindformulierung mit AE F107892. Response to Level C Deficiency letter. Date of submission unknown., DACO: 5.8

4.0 Impact on the Environment

PMRA 948720 Estimation of octanol-water partition coefficient (log Kow) of AE F059411, AE 000119, and AE 0034855. Report Date 10 November 2004. Report Number B004818.

PMRA 1064396 Estimation of octanol-water partition coefficient (log Kow) for Iodosulfuron (AE F115008) using KOWWIN (Vers. 1.6). Report Date 9 August 2005. Report Number B004818 (Addendum)

5.0 Value

No additional references.

